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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,131	06/02/2000	Marc Delcourt	1184-00	6329

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EXAMINER
FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
1627	

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/586,131	DELCOURT, MARC	
	Examiner	Art Unit	
	Tomas Friend	1627	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Change of Examiner's Name

The name of the examiner of this application has changed from Thomas Prasthofer to Tomas Friend.

Status of the Application

Receipt is acknowledged of a response to a notice of non-responsive amendment on 06 March 2002 (Paper No. 12).

Status of the Claims

Claims 1-20 were pending in the present application. Claim 20 was withdrawn from consideration by the Examiner as being drawn to a non-elected invention Group IV. Applicant indicates in the remarks of Paper No. 10 that the amendment received 24 September 2001 cancels claim 11. While claim 11 is not present in the "clean copy" of the pending claims, no formal amendment has been made canceling claim 11. Consequently, claim 11 is still pending. Claim 20 is missing from the clean copy of the claims, yet applicant indicates that claim 20 is pending. Newly added claims 21 and 22 are withdrawn from further consideration (see restriction below).

Claims 1-19 are pending and examined on their merits.

Restriction and Election by Original Presentation

1. Newly submitted claims 21 and 22 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly added claims are drawn to an isolated clone and a process for identifying an individual clone. The two new claims represent two new restriction groups;

Group V, claim 21, drawn to an isolated intact clone of the target nucleic acid of claim 1, classified in class 536, and various subclasses including 22.1-24.32

Group VI, claim 22, drawn to a process of characterizing the clone of claim 21, classified in class 935, subclass 19.

A. Groups I-III and Group V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the intact clone of Group V can be made using traditional cloning techniques such as isolation of insert DNA and cloning into restriction sites as well as using the process of Groups I-III.

B. Groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case process of Group VI can be used to characterize any cloned DNA and the clone of Group V can be characterized, for example, by Southern blot or sequencing without prior cleavage.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21 and 22 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Withdrawn Objections/Rejections

2. The following objections and rejections are withdrawn:

A. The objections to claims 1-19 over various informalities are withdrawn in response to applicant's amendment.

B. The rejections of claims 1-19 under 35 U.S.C. 101 and 112 for lacking a specific and substantial utility are withdrawn in response to applicant's arguments.

C. The rejections of claims 1-19 under 35 U.S.C. 112, first paragraph, (enablement) are withdrawn in response to applicant's arguments.

D. The rejections of claims 1, 2, 5, 6, 9, and 12-15 under 35 U.S.C. 112, second paragraph, are withdrawn in response to applicant's amendment.

Maintained Objections/Rejections

The statutory basis for each of the following rejections may be found in a prior office action.

6. Claim 11 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim for the reasons provided in Paper No. 8.

Applicant has indicated that claim 11 has been cancelled but the record is not clear with respect to the status of claim 11 (see Status of the Claims above).

New Grounds of Rejection - 35 U.S.C. 112, first paragraph

7. Claims 1-19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 16 have been amended to recite that the claimed process is "*useful to isolate an intact nucleic acid fragment and diagnose genetic disease.*" Using the claimed process would require undue experimentation by one of ordinary skill in the art.

Several factors are to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any required experimentation is "undue." These factors include:

1) the breadth of the claims
2) the nature of the invention
3) the state of the prior art
4) the level of one of ordinary skill
5) the level of predictability in the art
6) the amount of direction provided by the inventor
7) the existence of working examples
8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims encompass a process for isolating any clone of any DNA from any source in any vector to be useful in any genetic disease in any organism, including any plant, insect, prokaryote, reptile, or mammal. The fragments used in the process may encode any protein or RNA or be homologous to any other nucleic acid. All methods of screening for a characteristic of a nucleic acid fragment and/or its expression products are encompassed by the claims. These include methods to detect expression products of the DNA fragment, the presence of the fragment within clones, or any other "*known characteristic.*"

The level of predictability in the art for this process is low. A DNA fragment may have a "*known characteristic*" such as a length of 1 kilobase, a particular melting temperature, or confer antibiotic resistance to a cell transformed with a clone expressing the fragment. The predictability of using any DNA with any known characteristic to diagnose genetic disease is very low, particularly since no guidance is provided in the specification nor limitation recited in the claims that would provide a reasonable expectation that the fragment present in the isolated clone is in any way related to a genetic disease. There is no correlation between the library or isolated clone or fragment and a genetic disease.

The amount of direction provided by the inventor is not adequate to enable one of ordinary skill in the art to use the claimed invention. No guidance as to nucleic acid selection, methods of screening, or characteristics to screen for is provided. Only a general concept of how the method may be applied to the diagnosis of genetic disease is provided on pages 28-29 of the specification.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure is great. One using the invention must determine a correlation between

a genetic disease and a DNA fragment. For a known genetic disease with a known gene, a clone of the DNA and several mutants would, of course, already be available. For a genetic disease for which the associated or defective DNA sequence is not known, a correlation between the disease and the characteristic to be screened for must be established. Whether the relationship between a DNA a genetic disease is the use of the DNA as a probe, or the DNA is a part of a gene directly involved in the disease, the amount of research required can be years to decades.

The present application fails to provide a single example demonstrating the use of the claimed process to clone any gene and does not provide guidance for how to use the process to produce a single clone useful for the diagnosis of a single genetic disease.

For the reasons provided, undue experimentation would be required of one of ordinary skill in the art to use the claimed invention.

New Grounds of Rejection - 35 U.S.C. 112, second paragraph

8. Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 16 recite the limitation "*said method*" in line 2. There is insufficient antecedent basis for this limitation in the claims.

B. Claims 1 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: relationships between the structures (sequences of fragments or characteristics of fragments and diagnosing a genetic disease.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
18 May 2002

DR. JYOT[illegible]KAT PH.D
SUPERV[illegible] EXAMINER
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